

**TRANSMITTAL OF APPEAL BRIEF (Small Entity)**Docket No.  
**BIO-P0001-02**

In Re Application Of:

Eldon H. Nyhart, Jr.

APR 13 2007

Application No.

10/045,550

Filing Date

October 26, 2001

Examiner  
Loan H. Thanh

Customer No.

27268

Group Art Unit

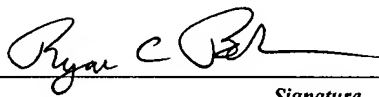
3763

Confirmation No.

Invention:

**MANUFACTURING METHODS FOR AN APPARATUS FOR THE CONTROLLABLE  
MODIFICATION OF COMPOUND CONCENTRATION IN A TUBE**COMMISSIONER FOR PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

☒ Applicant claims small entity status. See 37 CFR 1.27The fee for filing this Appeal Brief is: **\$250.00**☒ A check in the amount of the fee is enclosed.☐ The Director has already been authorized to charge fees in this application to a Deposit Account.☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 02-0390 I have enclosed a duplicate copy of this sheet.☐ Payment by credit card. Form PTO-2038 is attached.**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**  
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Dated: April 9, 2007

Ryan C. Barker, Reg. No. 47,405  
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Facsimile 317-237-1000**COPY**I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on  
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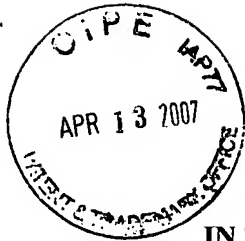
(Date)

Signature of Person Mailing Correspondence

D. Cwiklinski

Typed or Printed Name of Person Mailing Correspondence

cc:



PATENT  
Attorney Docket No. BIO-P0001-02

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of

Applicants:	Nyhart, Jr.	)	
		)	
Application No.:	10/045,550	)	Group Art Unit: 3763
		)	Examiner: Thanh, L.
		)	
Filed:	October 26, 2001	)	
		)	
For:	MANUFACTURING METHODS FOR	)	
	AN APPARATUS FOR THE	)	
	CONTROLLABLE MODIFICATION OF	)	
	COMPOUND CONCENTRATION IN A	)	
	TUBE	)	

**APPEAL BRIEF**

Mail Stop Appeal Brief-Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is an appeal of the Final Official Action dated November 3, 2006 issued in respect of the above-identified application, finally rejecting claims 57-65 and 104-106. Pending claims 57-65 and 104-106 and withdrawn claims 107-140 are provided in the attached claims appendices.

**I. Real Party in Interest**

The real party in interest is Biosynergetics, Inc., located at P.O. Box 5045, Zionsville, IN 46077.

**II. Related Appeals and Interferences**

There are no other appeals or interferences known to Appellant, the Appellant's legal representative, or assigns which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

### **III. Status of Claims**

Allowed claims:	None
Claims objected to:	None
Claims rejected:	57-65 and 104-106
Claims appealed:	57-65 and 104-106

### **IV. Status of Amendments**

There are no outstanding Amendments.

### **V. Summary of Claimed Subject Matter**

The following explanation of the subject matter defined in each of the independent claims is provided with reference to page, paragraph, and line numbers in the specification, and the drawings by reference characters as required by §41.37(c)(v). These references are made to a specific embodiment(s) disclosed in the application and do not limit the scope of the independent claims to the specific embodiment(s) and should not necessarily be considered to be exhaustive.

#### **A. Claim 57**

The subject matter defined in claim 57 relates to a method of providing a desired compound into a system. The method includes the use of a polymer matrix that contains the desired compound. When it is desired to release the compound, the polymer matrix is exposed to energy such as light radiation. The radiation breaks the bonds between the matrix and the compound, and the compound is released from the material such that it can diffuse into infusate. [Paragraph 0037]

The energy input is operated via a controller. The controller receives an input signal and controls a laser to release the compound from the matrix. [Paragraph 41]. The input from the controller to the laser may take the form of a fractal geometric curve. [Paragraphs 87 and 89].

With such compound, matrix, controller, and fractal input for the laser, the matrix material with the compound bonded thereto is placed in fluid communication with a desired system. The fractal based output from the controller is then provided as input to the laser, used to operate the laser, and provides energy to the matrix material to effect release of the compound into the system. [Paragraph 90].

## **VI. Grounds of Rejection to be Reviewed on Appeal**

Claims 57-59, 62, 64, and 105-106 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,086,582 to Altman et al. (hereinafter "Altman"). Claim 60 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Altman in view of U.S. Patent No. 6,028,068 to Chupakhin et al. (hereinafter "Chupakhin"). Claim 61 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Altman in view of U.S. Patent No. 4,789,673 to Donatsch et al. (hereinafter "Donatsch"). Claim 63 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Altman. Claims 65 and 104 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Altman in view of U.S. Patent No. 4,146,029 to Ellinwood, Jr. (hereinafter "Ellinwood").

## **VII. Argument**

### **A. Claims 57-59, 62, 64, and 105-106. Rejections under 35 U.S.C. §102- Altman**

The rejections of claims 57-59, 62, 64, and 105-106 depend on Altman. As discussed in greater detail below, Altman fails to teach a fractal based control signal. The Final Official Action admits as much, but then claims that such a feature is inherent.

#### **i. Altman**

Altman relates to a CARDIAC DRUG DELIVERY SYSTEM and discloses a catheter for administering a therapeutic agent locally within cardiac tissue. The Examiner has focused on the embodiment shown in Fig. 10b. Accordingly, that embodiment will be discussed herein.

Electrical connections are made at crimp 1050 and 1072 within the catheter. The connections 1050, 1072 have an electrical path between them which is defined by resistive heating element 1052 which passes through a reservoir 1056. Within reservoir 1056 is a fluid gas mixture which provides a constant pressure at human body temperature. This pressure is transmitted via a plate 1058 to a drug matrix 1060. The pores surrounding matrix 1060 are filled with agents in fluids. As electrical energy is delivered to resistive heating element 1052, the temperature of the fluid within reservoir 1056 increases. This increases the pressure within reservoir 1056 to cause expansion of bellows 1054 and to apply pressure to matrix 1060. This forces the agent containing fluid from within the matrix 1060 into proximal end of needle delivery system 1074 and out through the distal end of the needle into the heart wall.

The catheter is connected to an external controller and power source. The device senses cardiac activity through the surface of the drug delivery structure. When the heart experiences an arrhythmic event, the controller identifies the event and activates the energy source which delivers the drug to the heart. If no arrhythmia is sensed, the device is maintained in a monitoring mode.

As described above, Altman fails to teach or suggest "preparing a control signal using fractal mathematics" as required by claim 57.

*ii. Altman does not inherently include fractal based signals*

Independent claim 57 is directed to a method for providing a compound to a system. Claim 57 requires, in part, "preparing a control signal using fractal mathematics" and "operating the controller with the control signal." The final Official Action admits that such a control signal is not expressly taught by the reference. However, the Official Action takes the position that such a feature is inherent in the Altman reference. As grounds for doing so, the Official Action states "the computer/controller is inherently producing fractal mathematics since fractals are generated by an iterative process – doing the same thing again and again. The computer/controller has this factor built in."

In order for something to be inherent, it must necessarily be present. Many things are produced by an iterative process. Showing that a computer has an iterative process does not teach, necessitate, or inherently include that fractal mathematics are thereby utilized. Additionally, the Official Action states that "[f]ractals also have the property that when you magnify them they still look much the same. The device of Altman produces the same control signal to release the compound." Applicant fails to understand the relevance of this statement. First, the Official Action fails to show or even suggest that the signal of Altman has "the property that when you magnify [it, it] still [looks] much the same." Accordingly, the Official Action fails to point out where the teaching of supposed similarity in signals is found, let alone to then require the leap in logic that such a similarity results in use of fractal mathematics. Even assuming that the signal of Altman looks the same when magnified, showing that a provided signal has a characteristic in common with a fractal based signal does not teach, suggest, necessitate, or inherently require a fractal based signal.

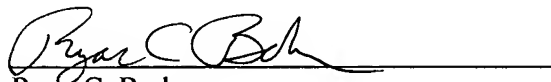
Accordingly, the Official Action fails to cite a reference that expressly teaches a control signal utilizing fractal mathematics, and the arguments for the inherency of such a feature fail to show that the fractal mathematics are necessarily present. The Official Action admits that fractal mathematic base signals are not expressly taught by Altman. A recitation

of characteristics of fractals, followed by uncited and unsubstantiated statements that a signal taught by Altman shares those characteristics can not suffice to show inherency. Indeed, even if the statements were cited and substantiated, such similar characteristics do not suffice to show inherency. For at least the above reasons, Applicant believes that claim 57 and claims 58-65 and 104-106 which depend from claim 57 are believed to be in condition for allowance. Such allowance is respectfully requested.

### **VIII. Conclusion**

In view of the above, Applicants respectfully submit that the present application is in order for allowance and respectfully request the Honorable Board of Appeals to direct the withdrawal of the rejections of the Final Official Action and the issuance of a Notice of Allowance.

Respectfully submitted,



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### **CERTIFICATE OF MAILING**

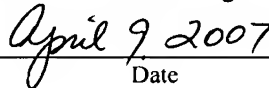
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Signature

D. Cwiklinski

Printed Name of Person Mailing Correspondence



Date

## CLAIMS APPENDIX

1.-56. (Canceled)

57. (Previously presented) A method for providing a compound to a system comprising:

providing a compound releasably captured within a matrix material, the compound being releasable upon receiving an energy input, a source of energy, and a controller operatively connected to the source and using a control signal to operate the source;

preparing a control signal using fractal mathematics;

placing the matrix material and captured compound in fluid communication with the system; and

operating the controller with the control signal and providing energy to the matrix material sufficient to release a portion of the compound into the system.

58. (Previously presented) The method of claim 57 wherein the compound elicits a response of the system and the control signal is based on the response.

59. (Previously presented) The method of claim 57 wherein the system is the circulatory system of a biological unit and the response is a response of the heart.

60. (Previously presented) The method of claim 57 wherein the system is the neurological system of a biological unit and the therapeutic agent is an anesthetic.

61. (Previously presented) The method of claim 57 wherein the system is the neurological system of a biological unit and the therapeutic agent is a neurotransmitter.

62. (Previously presented) The method of claim 57 wherein the matrix material is attached to a catheter and the catheter is inserted into the system.

63. (Currently amended) The method of claim 57 wherein the control signal has a frequency content generally less than about 1 hertz.

64. (Previously presented) The method of claim 57 wherein said operating includes releasing predetermined amounts of compound at predetermined intervals.

65. (Previously presented) The method of claim 57 wherein said operating includes releasing variable amounts of compound at predetermined intervals.

66.-103. (Canceled)

104. (Previously presented) The method of claim 57 wherein said operating includes releasing variable amounts of compound at variable intervals.

105. (Previously presented) The method of claim 57 wherein said providing includes a sensor operatively connected to said controller, and a catheter, the matrix being attached to the catheter, and which further comprises sensing a second response of the system, wherein said operating is in response to said sensing.

106. (Previously presented) The method of claim 57 wherein the control signal is based on a fractal representation of the system.

107. (Withdrawn) An apparatus for delivering fluid, comprising:  
a tube having an interior surface and an exterior surface;  
an inert polymer matrix attached to the interior surface, said polymer matrix defining a lumen therethrough for flow of the fluid; and  
a compound covalently bonded to said matrix and releasable from said polymer matrix upon exposure to electromagnetic energy.

108. (Withdrawn) The apparatus of claim 107 wherein said compound is releasably captured to said polymer matrix by photolabile bonds.

109. (Withdrawn) The apparatus of claim 108 wherein said polymer matrix is a hydrogel.



110. (Withdrawn) The apparatus of claim 109 which further comprises a source of electromagnetic energy for releasing said compound from said polymer matrix and a controller operably coupled to said source.

111. (Withdrawn) The apparatus of claim 110 wherein said source is a laser and said tube transmits energy from said laser into said polymer matrix.

112. (Withdrawn) The apparatus of claim 111 wherein said tube includes an opaque coating on the exterior surface of limiting the escape of radiation from the exterior surface.

113. (Withdrawn) The apparatus of claim 111 wherein said tube includes a reflective coating on at least one of the interior surface or the exterior surface for reflecting radiation into said polymer matrix.

114. (Withdrawn) The apparatus of claim 107 wherein said tube is adapted and configured to transmit coherent radiation into said polymer matrix.

115. (Withdrawn) The apparatus of claim 114 wherein said tube includes an opaque coating on the exterior surface for limiting the escape of radiation from the exterior surface.

116. (Withdrawn) The apparatus of claim 114 wherein said tube includes a reflective coating on at least one of the interior surface or the exterior surface for reflecting radiation into said polymer matrix.

117. (Withdrawn) The apparatus of claim 114 which further comprises a fiber optic cable for coupling a source of coherent radiation to said tube.

118. (Withdrawn) The apparatus of claim 107 which further comprises a source of electromagnetic energy for releasing said compound from said polymer matrix and a controller operably coupled to said source of energy, said controller operating said source of energy to provide energy to said polymer matrix in a fractally-based pattern.

119. (Withdrawn) The apparatus of claim 118 wherein said compound is releasably captured to said polymer matrix by covalent photolabile bonds and said source is a laser generating energy capable of breaking the bonds.

120. (Withdrawn) The apparatus of claim 119 wherein said source is a laser irradiating the polymer matrix with laser pulses of varying radiation intensity.

121. (Withdrawn) The apparatus of claim 119 wherein said source is a laser irradiating the polymer matrix with laser pulses of varying radiation intensity.

122. (Withdrawn) The apparatus of claim 107 wherein said compound is a first compound bonded to said matrix by first photolabile bonds, and which further comprises a second compound different from said first compound bonded to said matrix by second photolabile bonds, said second compound being releasable from said polymer matrix upon exposure to electromagnetic energy.

123. (Withdrawn) The apparatus of claim 122 wherein the first photolabile bonds are releasable by a first wavelength of light and the second photolabile bonds are releasable by a second wavelength different than the first wavelength.

124. (Withdrawn) The apparatus of claim 122 wherein said tube includes an opaque coating on the exterior surface for limiting the escape of radiation from the exterior surface.

125. (Withdrawn) The apparatus of claim 107 wherein said outer sheath includes a first interior section and a second interior section, said first section including a first portion of polymer matrix, said second section including a second portion of polymer matrix, wherein said compound is a first compound releasably captured by first photolabile bonds to said first portion of said polymer matrix and which further comprises a second compound releasably captured by second photolabile bonds to said second portion of said polymer matrix.

126. (Withdrawn) The apparatus of claim 125 wherein the first photolabile bonds are releasable by a first wavelength of light and the second photolabile bonds are releasable by a second wavelength different than the first wavelength.

127. (Withdrawn) The apparatus of claim 125 wherein said tube includes an opaque coating on the exterior surface for limiting the escape of radiation from the exterior surface.

128. (Withdrawn) A method for providing a compound into a flowing fluid, comprising:

providing a section of tubing, the tubing having an interior with a layer of an inert polymer matrix material attached to the interior, the matrix including a compound covalently bonded thereto;

flowing a fluid through the interior of the tubing and over the matrix material;

applying electromagnetic energy to the matrix material; and

releasing the compound from the matrix material into the fluid by said applying energy to the matrix material.

129. (Withdrawn) The method of claim 128 wherein the section of tubing is a catheter, the matrix material is a polymer material, the fluid is infusate, the compound is a therapeutic agent, and which further comprises providing a mixture of infusate and the first compound to a person.

130. (Withdrawn) The method of claim 128 which further comprises forming a lumen by the matrix material, wherein said flowing is through the lumen.

131. (Withdrawn) The method of claim 128 wherein said applying energy is by irradiating the matrix material with a laser.

132. (Withdrawn) The method of claim 129 wherein said applying energy is by irradiating the matrix material with a plurality of laser pulses of varying time duration.

133. (Withdrawn) The method of claim 131 wherein said applying energy is by irradiating the matrix material with a plurality of laser pulses of varying intensity.

134. (Withdrawn) The method of claim 128 wherein the fluid includes water and the matrix material is a hydrogel.

135. (Withdrawn) The method of claim 128 wherein said flowing a fluid is flowing a fluid withdrawn from a biological unit.

136. (Withdrawn) The method of claim 135 which further comprises conditioning the fluid and returning the bodily fluid to a biological unit.

137. (Withdrawn) The method of claim 128 wherein said fluid is infusate being provided to a person at a constant volumetric flow rate and wherein said releasing does not alter the flowrate.

138. (Withdrawn) The method of claim 128 wherein said providing includes a first container which includes the fluid, a second container for receiving a flow of the fluid including the released first compound.

139. (Withdrawn) The method of claim 128 which further comprises delivering the first compound systemically to the biological unit.

140. (Withdrawn) The method of claim 128 wherein said providing includes a source of light, the section of tubing has walls and an interior surface, the layer of matrix material is bonded to the interior surface, the tubing has an exterior surface coated to discourage transmission of light therethrough, and said applying energy is by light transmitted from the source through the walls.

## **EVIDENCE APPENDIX**

Appellant is unaware of any evidence entered into the record.

**RELATED PROCEEDINGS APPENDIX**

Appellant is unaware of any proceeding to identify pursuant to 37 CFR §41.37(c)

(1)(ii).